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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,075	06/01/2001	Allan Svendsen	10038.200-US	4049

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EXAMINER	
SLOBODYANSKY, ELIZABETH	
ART UNIT	**PAPER NUMBER**
1652	12

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/873,075	SVENDSEN ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17,18,22,23 and 28* is/are pending in the application.

4a) Of the above claim(s) *3,5,6,14,15,17,18,22,23 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15,17,18,22,23 and 28* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The preliminary amendment filed concurrently with the application on June 1, 2001 canceling claims 16, 19-21, 24-27, 29-32 has been entered.

Claims 1-15, 17, 18, 22, 23 and 28 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4 (in part), 7 and 9-13, drawn to a variant cutinase, classified in class 435, subclass 197.

II. Claims 3 and 4 (in part), drawn to a variant cutinase, classified in class 435, subclass 197.

III. Claims 5 and 6, drawn to a variant cutinase, classified in class 435, subclass 197.

IV. Claim 8, drawn to a variant cutinase, classified in class 435, subclass 197.

V. Claims 14, 15 and 17 (in part), drawn to a DNA encoding the variant of claim 1, a vector containing thereof and a method of making a variant of claim 1 using a host cell, classified in class 435, subclass 197.

VI. Claim 17 (in part), drawn a method of making a variant of claim 3 using a host cell, classified in class 435, subclass 197.

VII. Claims 18 and 22, drawn a method of making a variant by mutation, classified in class 435, subclass 440.

VIII. Claim 23, drawn a method of making of a cyclic oligomer, classified in class 435, subclass 41.

IX. Claim 28, drawn a method of treating the yarn with a variant cutinase, classified in class 435, subclass 41.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are patentably distinct as drawn to materially different polypeptides having different structures, functions and effects.

Inventions I-II and V-VI are patentably distinct because a polypeptide and a DNA are different compounds each with its own chemical structure and function, and they have different utilities. A DNA molecule of inventions V and VI can be used for the production of a polypeptides of invention I and II, respectively, and as a hybridization probe. A polypeptide of invention I or II can be obtained by a materially different method such as by the chemical synthesis.

Inventions V-VI and I-II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case mutation can be used for the production of various polypeptides and the claimed variant can be produced by the chemical synthesis.

Inventions I and VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a variant of invention I can be used for the treatment of an isolated chemical compound of invention VIII and for treating the yarn of inventions IX. Methods of inventions VIII and IX use different protocols and compounds and have different utilities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: corresponding to the specific mutations recited in the claims.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15, 17, 18, 22, 23 and 28 *are generic.*

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Jason Garbell on January 2, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1, 2, 4 (in part), 7 and 9-13, with election of species of A130. Affirmation of this election must be made by applicant in replying to this Office action. In view of election of species of A130, Group IV, claim 8, which also comprises A130, has been rejoined with Group I.

Claims 3, 5, 6, 14, 15, 17, 18, 22, 23 and 28 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

See, for example, page 3, line 4.

The disclosure is objected to because some abbreviations are not defined such as , for example, "DSC", "Cp" (page 28, lines 5-8).

Claim Objections

Claim 4 is objected to as dependent from non-elected claim 3. Appropriate correction is required.

Claim 8 is objected to because a) it does not end in a period, b) it should have "or" between "cc)" and "dd)' and should have "comprises" instead of "comprise" on line 1. Claim 13 is objected to because "5° C" should be typed instead of "5°".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to a variant of a parent fungal cutinase which comprises substitution of at least one amino acid residue corresponding to position A4, T29, A88, N91, A130, Q139, I169, I178 or R189 in the cutinase of *Humicola insolens* strain DSM 1800 when the variant is more thermostable than the parent cutinase. Claims 2, 4 and 9-13 depend from claim 1. Claim 8 is directed to a variant of a parent fungal cutinase which comprises a substitution of at least one amino acid residue corresponding to one or more of the specific positions in the cutinase of *Humicola insolens* strain DSM 1800.

Claim 4 limits the structure of the parent cutinase "to at least 50% homologous to the cutinase of *H. insolens* strain DSM 1800". Therefore, in claims 1, 2, 4 and 8-13, the total number of possible substitutions relative to the cutinase of *H. insolens* strain DSM 1800 (SEQ ID NO:1, page 3, lines 8-10) is not limited. This amounts to any amino acid structure that is not necessarily homologous to SEQ ID NO:1. Regarding claim 7, while the number of substitutions relative to the parent cutinase is limited, the structure of the parent cutinase is not. Thus, the claims are drawn to an enormous genus of a cutinases with the specific properties as recited in claims 1, 2, 4, 7 and 9-13 and to a cutinase with any properties of claim 8.

Applicants disclose a number of specific mutants of SEQ ID NO:1 (pages 5-6 and 26-27). In the mutants with the most substitutions, said substitutions constitute no more than about 8% of SEQ ID NO:1. This is insufficient to describe the entire structure because less than 8% of the structure does not posses a cutinase activity. Moreover, the specification fails to describe any other identifying characteristics or properties other than the "functionality" of being "cutinase". With regard to a cutinase with an increased thermostability, the specification in addition fails to provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 1, 2, 4 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific mutants of SEQ ID NO:1 that are more thermostable than the "reference" cutinase and/or hydrolyze BETEB, does not reasonably provide enablement for a cutinase having unknown homology to SEQ ID NO:1 comprising the specific mutations and that either hydrolyzes BETEB and has the same or greater thermostability than the parent or "reference" cutinase or has any unspecified properties. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim 1 and claims 2 and 9-11 dependent therefrom, are directed to a cutinase of an unknown structure comprising substitutions at the specific positions that is more thermostable than the parent cutinase. Claim 4 depends from claim 1 and limits the structure of the parent cutinase "to at least 50% homologous to the cutinase of *H. insolens* strain DSM 1800". Claim 7 depends from claim 1 and limits the structure of a variant to "one to twenty of such substitutions" without limiting the strucutre of the parent cutinase. Claim 12 depends from claim 1 and limits the enzymatic activity to hydrolytic towards BETEB. Claim 13 depends from claim 1 and limits a denaturation temperature to at least 5° higher than the parent cutinase. Claim 8 is drawn to a cutinase comprising specific mutations and having unknown homology to SEQ ID NO:1.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of cutinase enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequences of the specific mutants (pages 25-26).

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass variant cutinases with unknown homology to SEQ ID NO:1 and having the

requisite properties or any properties because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting cutinase activity; (B) the general tolerance of cutinase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any cutinase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of modifications in SEQ ID NO:1.

Furthermore, regarding claim 7, it may be (because the exact variant is unknown) enabling for a *H. insolens* variant cutinase that is more thermostable than the reference cutinase, is not enabling for a variant that is more thermostable than the native *H. insolens* cutinase. The specification teaches the variants that are more thermostable than the reference cutinase, i.e., a cutinase that has 5 additional mutations (pages 26-27). It does not teach a variant comprising the specific recited mutations and not having mutations present in the reference cutinase that is more thermostable than the native cutinase. Nor does the specification provides guidance as to how to make such variant.

With regard to claim 13, the specification is enabling for the "three variants" that have a denaturation temperature 3° C higher than the reference cutinase but is not enabling for a variant with a denaturation temperature 5° C higher (page 28, lines 9-11).

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without necessary guidance discussed above, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Claims 1, 2, 4, 7 and 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the following. The claims are drawn to a variant cutinase that is more thermostable than the parent cutinase. The specification provides the list of variants of cutinase and states that three of them are more thermostable than the reference cutinase (page 28, lines 4-11). The specification does not disclose which three variants from 29 variants disclosed on pages 26-27 are more thermostable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "a variant of a parent fungal cutinase". This term is unclear because it does not require for a variant to be a cutinase. Amending the claims to "a variant cutinase obtained from a parent fungal cutinase by ..", for example, is suggested.

Further, the claims refer to "residue corresponding to position ... in the cutinase of *H. insolens* strain DSM 1800 (*H. insolens* cutinase numbering)". Since said numbering is defined as in SEQ ID NO:1, it would be more clear if instead of "(*H. insolens* cutinase numbering)", SEQ ID NO:1 is recited (page 3, lines 8-10).

Claim 2 is indefinite as referring to "a preceding claim". The number of the base claim (claim 1) should be recited.

Claim 4 is confusing as reciting "an amino acid sequence which can be aligned with the cutinase of *H. insolens* strain DSM 1800". In order to locate residue corresponding to a specific position in the cutinase of *H. insolens* strain DSM 1800, it is necessary to align the sequences. Therefore, claim 4(b) does not define the limitation of claim 1. On the other hand, sequences with drastically different homology to the cutinase of *H. insolens* strain DSM 1800 can be aligned thereto rendering the metes and bounds of the claim unascertainable.

Claim 7 is unclear because "has" can be construed as open language. Amending the claim to "a variant cutinase that differs from the parent cutinase by one to twenty substitutions", for example, is suggested.

Claim 8 is confusing as reciting "a substitution of at least one amino acid residue". The claim recites a list of single mutations and combinations of mutations. It reads on a single mutation within the combination.

Claims 9 and 10 depend from claim 1. Therefore, the recitation of "(*H. insolens* cutinase numbering)" is redundant.

Regarding claims 12 and 13, the phrase "particularly" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Furthermore, regarding claim 13, denaturation temperature is known to depend from pH. Without knowing the exact pH under which the measurement was done, it is impossible to know the metes and bounds of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yao et al.

Yao et al. (GenBank accession AAA03470) teach the amino acid sequence of the cutinase from fungus *Alternaria brassicicola* (SwissProt-40 accession P41744). Said sequence is more than 60% identical to SEQ ID NO:1 and has valine in position corresponding to A130 in SEQ ID NO:1.

Therefore, the Yao et al. reference anticipates claim 8. Claims 1, 2, 4, 7 and 9-13 are anticipated because the *Alternaria brassicicola* cutinase is more thermostable than *H. insolens* cutinase.

Claims 1, 2, 4 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Swelgard et al.

Swelgard et al. teach the amino acid sequence of the cutinase from fungus *Madnaporthe grisea* (SwissProt-40 accession P30272). Said sequence is more than 60% identical to SEQ ID NO:1 and has valine in position corresponding to A130 in SEQ ID NO:1.

Therefore, the Swelgard et al. reference anticipates claim 8. Claims 1, 2, 4, 7 and 9-13 are anticipated because the *Madnaporthe grisea* cutinase is more thermostable than *H. insolens* cutinase.

Claims 1, 2, 4 and 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ettinger et al.

Ettinger et al. teach the amino acid sequence of the cutinase from fungus *Glomerella cingulata* (SwissProt-40 accession P11373). Said sequence is more than 58% identical to SEQ ID NO:1 and has valine in position corresponding to A130 in SEQ ID NO:1.

Therefore, the Ettinger et al. reference anticipates claim 8. Claims 1, 2, 4, 7 and 9-13 are anticipated because the *Glomerella cingulata* cutinase is more thermostable than *H. insolens* cutinase.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4 and 7-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35, 37, 38, 47, 48 of copending Application No. 09/857,068. Although the conflicting claims are not identical, they are not patentably distinct from each other because base claim 35 in '068 is directed to a variant cutinase with a substitution within residues 3-12, 20-60, 130-132, 176-182 of *Humicola insolens* strain DSM 1800. Base claim 1 of the instant invention is directed to a variant cutinase with a substitution corresponding to positions in *Humicola insolens* strain DSM 1800 that fall within residues recited in claim 35, such as A130, for example. It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a variant with a substitution at each position within the fragments disclosed in '068.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

March 6, 2003